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March 20, 1998

Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Dr., rm. 1-23
Rockville, Maryland 20857

Re: Docket No. 97N-0477

Dear Sir or Madam:

Karl Storz Endoscopy-America, Inc. (KSEA) hereby submits the attached response to FDA's solicitation for comment from device manufacturers in regards to FDA's "intention to review and, as necessary, to revise or to amend its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices and the persons who refurbish, recondition, rebuild, service, or remarket such devices." KSEA understands that the Agency is "considering these actions because it believes evolving industry practices warrant reevaluation of current policy and the application of certain regulatory requirements in order to ensure that particular remarketed devices meet suitable performance requirements for their intended uses, and are as safe as the originally marketed finished device."

KSEA is responding specifically to questions #2 and #4 posed by FDA in Section V of the "Refurbishers, Rebuilders, Reconditioners, Servicers, and "AS IS" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information" Notice ("Notice"):

#2 "what evidence exists regarding the actual problems with the safety and/or performance of remarketed devices that are the result of remarketing [by servicers]? Specific examples should be submitted."

#4 "should refurbishers, 'as is' remarketers, and servicers be subject to the same or different regulatory requirements?"

This document presents evidence pertaining to actual problems that impact the safety and effectiveness of Karl Storz endoscopes, insulated electrosurgical instruments, noninsulated instruments and video cameras that have been repaired by independent servicers. KSEA has evaluated damaged Karl Storz endoscopes and instruments that have been repaired by specific independent servicers. The results of this study revealed

97N-0477

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that independent servicers are not capable of consistently performing effective medical device repairs. In addition, KSEA has reviewed complaint, repair and legal records for evidence of substandard repairs by independent servicers. KSEA's results from both the study and records research reveals that typical problems resulting from repair by independent servicers included inferior optical quality in endoscopes, inadequate insulation of electrosurgical instruments, incorrect assembly of surgical instruments and impaired function of video cameras. It is likely that many of these problems could cause or contribute to patient or healthcare personnel injury if the device were used again in its impaired state. Specific examples of Karl Storz devices that were repaired incorrectly by independent servicers are presented in detail in sections I-II of this response which in turn demonstrates that servicers:

- Do not return devices to their original published specifications
- Do not validate that repaired devices perform according to the manufacturer's specifications
- Do not use proper materials and components to repair devices
- Have limited knowledge of medical devices

Based upon this evidence, KSEA has concluded that servicers should be subject to the same regulatory requirements as the original device manufacturer. Karl Storz produces and maintains its devices in compliance with 21 CFR 820 Quality Systems Regulations to ensure that Karl Storz devices are safe and effective. The evidence that KSEA has compiled indicates that independent servicers cannot always perform a satisfactory repair on Karl Storz devices; compliance of independent servicers with the Quality System Regulations will help to ensure that devices are repaired in such a manner that the device will be safe and effective in subsequent uses, and therefore reduce the potential health hazard to the public.

Although this communication is based primarily upon a series of repairs specifically performed in order to respond to the Notice, the conclusions are consistent with mounting complaint records and product liability actions, in which independent servicers have been implicated in faulty and substandard repairs.

The following sections provide the test and evaluation methods employed by KSEA to demonstrate that independent servicers cannot repair Karl Storz devices without negatively impacting the safety and effectiveness of these devices. Also following are the results and discussion of test results for endoscopes, insulated electrosurgical instruments, noninsulated instruments and video cameras that have been subjected to repair by independent servicers.

I. REPAIR AND EVALUATION OF ENDOSCOPES AND INSTRUMENTS.

A. Rigid Endoscope repair

1. Methods

Six damaged rigid rod lens endoscopes (models 7200A, 27018A, 27005B, BA and 26006AA) were sent for repair to the following independent servicers:

- Integrated Medical Systems (IMS) Rigid Endoscope Repairs in Pembroke Pines, FL.
- Endocare in Greensboro, NC
- Precision Endoscopy of America, Inc. Southern California Service Center in Laguna Hills, CA
- Fibertech of Baltimore MD
- Surgitech in Miami, FL.

These servicers were selected because they are well-known, reputable, established companies that have been used by customers to repair Karl Storz devices. Therefore, it was assumed that the best possible repairs would be forthcoming from these firms because of their resources and expertise, unlike what might be found by using smaller, less-experienced independent servicers.

Four additional endoscopes were returned to KSEA for evaluation by a KSEA customer after the endoscopes were unsatisfactorily repaired by South Coast Surgical Services (Irvine, CA). All four of these endoscopes were included in this study.

The ten endoscopes described herein were of assorted sizes that ranged in diameter from 2.7 - 5.0 mm and in length from 10-30 cm.

The endoscope data was accumulated over a three month period following publication of "Refurbishers, Rebuilders, Reconditioners, Servicers, and "AS IS" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information" Notice in the Federal Register (12/23/97). Because of the time available to respond to the Notice, only a limited study could be completed. *However, no data was withheld from this report* and all evaluations conducted on the sampled devices are reported in their entirety herein.

Each of the first group of six endoscopes was visually evaluated by KSEA repair personnel in Charlton MA, before being sent out for repair. The second set of four endoscopes was received from the customer only after the endoscopes had been repaired by the independent servicer, therefore KSEA was not able to evaluate the devices in the "before" condition. Based upon customer input, KSEA is making the assumption that the

customer sent the endoscopes to KSEA immediately upon receipt from the independent servicer and that the endoscopes did not incur any further damage.

However, all ten endoscopes were evaluated after repair, both visually and by optical testing. The visual examination included evaluation of the condition of the shaft, eyepiece and rod lenses. The evaluation of the first group of six endoscopes also included measurement of angle of view and shaft length, and leakage detection. The optical tests included measurement of the following parameters: radiant output powers of the illumination system (illumination efficiency), relative powers through the imaging system (imaging transmission), field of view and optical resolution. A new, unused "reference" endoscope of the same model as the repaired subject endoscope was tested along with the subject endoscope for direct comparison.

The optical tests were used to quantify the quality of the endoscope's image. The "illumination efficiency" testing of the repaired endoscope and the reference endoscope initially compared the illumination power output of the endoscopes to that of the light cable. The outputs were measured in milliwatts (mW) and expressed as a percentage of the output through a standard Karl Storz fiber optic light cable (495NL). The values from the repaired endoscopes were then normalized to the reference endoscope.

The "imaging transmission" testing measured the output of light through the imaging system of the endoscope in mW, and then expressed as a percentage of the output of the reference endoscope. The values from the repaired endoscopes were then normalized to the reference endoscope.

The field of view is the angle formed by the two outer visual limits of the image, determining the diameter of the field of view or size of the object viewed. A narrow field of view magnifies the object and a wide field of view diminishes the object.

Resolution is a measurement of the ability to differentiate between two distinct and separate points. The test involves viewing a test pattern with the endoscope to determine the smallest set of lines that can be distinctly discerned. Results are given as line pairs (lp) per millimeter.

2. Results

Visual Results After Repair

Table 1 (found in Attachment 1) summarizes the results of visually examining the ten endoscopes; Attachment 3 contains representative photos of device damage.

As can be ascertained from Table 1, there was not one endoscope in the group of ten that was problem-free after repair by independent servicers. The evaluation of the

endoscopes resulted in five categories of problems remaining after repair by independent servicers: optical, dimensional, physical damage, incorrect reassembly and poor workmanship. Each problem is listed with details of the defects in the following paragraphs:

Optical:

- Eight endoscopes: out of focus
- One endoscope: no image due to a lens that had broken loose in the eyepiece (see photo 1)
- Two endoscopes: angle of view off by -2° to -4°

Dimensional:

- Two endoscopes: shafts were 1 mm too long

Physical damage:

- Two endoscopes: bent or dented shafts (see Photo 2)
- Three endoscopes: gouges at shaft/body junction, presumably from removing shaft for repair (see Photo 3)
- Two endoscopes: distal tip of shaft metal chipped/gouge (see Photo 4)
- Two endoscopes: cracked color coding ring
- One endoscope: distal lens chipped and scratched (see photo 5)

Incorrect reassembly:

- One endoscope: Eyepiece was positioned incorrectly
- Two endoscopes: Image indicator for orientation in wrong position
- One endoscope: Eyepiece ring on backwards and in wrong position

Poor workmanship:

- One endoscope: dirty distal lens and shaft (residue)
- One endoscope: multiple scratches on eyepiece

Optical Results After Repair

Tables 2 and 3 (found in Attachment 1) present the optical test data for the repaired and reference endoscopes; Attachment 2 contains optical resolution charts (Figures 1 and 2).

As illustrated in Tables 2 and 3, overall, seven of the 10 scopes that were repaired by independent servicers exhibited major differences in optical test quality as compared to the reference endoscopes. The test data for each optical test is summarized below.

Illumination efficiency:

- Seven of the ten endoscopes showed a decrease of 30-76% in the illumination efficiency in comparison to the reference endoscopes.

Imaging Transmission:

- Three of the ten endoscopes showed a decrease of 30-57% in imaging transmission in comparison to the reference endoscope.

Field of view:

- One of the ten endoscopes exhibited a 29% increase in the field of view in comparison to the reference endoscope with a resulting distortion of the image.

Optical resolution:

- One out of the ten endoscopes exhibited major changes in resolution in comparison to the reference endoscope.

3. Discussion of Endoscope Results

All ten endoscopes received substandard repairs regardless of which independent servicer performed the repair. All repaired endoscopes had defects that had a negative impact on the performance of the endoscope. Many of these problems could also present an increased safety risk to the patient in subsequent uses. These problems fell into five categories, including optical, dimensional, physical damage, incorrect reassembly and poor workmanship that are addressed as follows.

Optical:

An endoscope has one function: to provide visualization of the surgical site. In order to accomplish this, the device must present a clear, accurate and well illuminated image through the eyepiece to the surgeon. If there is no image, then obviously the endoscope cannot be used for the surgical or diagnostic procedure. If the image is distorted, out-of-focus or has poor resolution, then the chance of error by the surgeon increases. If the

endoscope image is poor, the surgeon may not be able to see the relevant anatomical structure, or he may not be able to see the structure clearly enough to perform the procedure or diagnose the problem. If the image is distorted, she may also misdiagnose the problem or not perform the surgery correctly. Therefore, it is critical that the endoscope optics perform within specification.

As shown in Table 1, eight of the ten endoscopes were out of focus and one had no image after repair by independent servicers. *In other words, 90% of the endoscopes repaired by independent servicers were returned from repair producing an unacceptable image.* This raises a serious concern about the quality of endoscope repairs by independent servicers and the safety and effectiveness of the devices they repair. Optical quality must be maintained or there will be an increase in the chances for misdiagnosis and surgical error.

Distortion of the image also presents a great risk to the patient. Decreased resolution or focus, or a change in the angle of view may not be noticed prior to surgery, and therefore could produce a safety hazard to the patient. For example, Table 2 shows the 27018A endoscope repaired by Surgitech was returned with a 29% greater field of view. An increase in the field of view would seem to be a positive change, however in this case the resolution of the endoscope in the center and edges of the image was altered in such a way that the resulting image is more curved (see Figure 1 in Attachment 2)) than the reference endoscope (see Figure 2 in Attachment 2). Therefore, the surgeon will see a curved line instead of a straight line, producing a confusing image and creating a greater margin for error.

The outputs of light though the imaging and illumination systems are equally as important as the optical quality of the image. The surgeon must have a well illuminated surgical site to diagnose or perform the surgical procedure correctly. Performing a procedure in a poorly illuminated site will only increase the chance for error by the surgeon. *70% of the endoscopes showed a decrease in illumination efficiency of 30% or more and 30% showed a decrease of 30% or more in imaging transmission after repair by independent servicers.*

The surgeon may compensate for the decreased illumination by increasing the power output on the light source to maximum. This could result in overheating of the light post that connects the fiber optic light cable to the endoscope, presenting a hazard to the user or the patient. Once again, this raises a serious concern about the quality of work done by the independent servicers and the safety and effectiveness of the endoscopes that they repair.

Dimensional:

Two of the endoscopes exceeded the device specification for length by 1 mm. This small deviation can cause problems when the device is used in conjunction with a protective sheath, e.g. resectoscope sheath, which is matched by size to the endoscope. An endoscope that protrudes too far from the sheath may interfere with other instrumentation, including electrosurgical instruments, electrodes and cutting loops, increasing the risk of arcing that can result in burns to both the patient and endoscope.

Physical damage:

Physical trauma to the shaft can cause breakage of the rod lenses and cause the image to deteriorate. This is the reason that many of the endoscopes in this study required repair. However, the image may also be impaired by damage to the distal lens or the eyepiece window. One of the 7200BW endoscopes repaired by South Coast Surgical was returned from repair to the customer with a scratch and a chip on the lens. This demonstrates a basic lack of expertise in the repair of endoscopes as this problem will certainly have a negative impact on the performance of the device. The chip on the lens could weaken it to the point that a minor impact during surgery could cause the lens to break and expose the patient to debris from the device, thus introducing yet another risk to the patient.

Other physical damage may not affect the image of the endoscope, but may present a safety hazard from the presence of sharp edges. *50% of the endoscopes repaired by independent servicers in this study had damage on the shaft in the form of small dents or bends, or shaved or chipped metal on the distal tip of the endoscope shaft.* (Examples of these defects are illustrated in Photos 2 and 4 in Attachment 1). The shaved areas on the distal tip present a safety hazard from the sharp edges that could come into contact with the patient. This also exposes material from underneath the protective top coating to cleaning and sterilization chemicals that can cause corrosion and degradation of the material.

Incorrect Assembly:

Two endoscopes suffered from incorrect reassembly of the device. Incorrect performance of relatively simple reassembly tasks, such as replacing the eyepiece ring correctly, or ensuring that the image indicator is in the correct position, indicate that there is a serious lack of knowledge of the most basic of device specifications.

Correct replacement of the eyepiece and the eyepiece ring ensures that the devices will produce a correct image and are sealed properly to prevent fluid intrusion. The image indicator is seen on the perimeter of the endoscope image. It is a small pointer that is used by the surgeon as a navigational marker relative to the position of the endoscope. If

the surgeon is accustomed to the pointer being in the specified position, the change in position could cause confusion to the surgeon.

Both of these problems could impact the performance and safety of the device.

Poor workmanship:

Poor workmanship is difficult to define, but is attributable to a lack of attention to detail. One endoscope in this study was returned with a dirty lens and residue on the shaft. Another was returned with multiples scratches on the eyepiece. The dirty scope reflects a lack of attention to detail which in this case will probably not impact the safety or performance of the device, assuming that the customer cleans the lens. There are customers that return endoscopes for repair for foggy image, never thinking that the problem may be a dirty lens.

The small scratches on the eyepiece may merely seem to be a cosmetic problem, but can trap proteinaceous materials and microorganisms, presenting a cleaning and sterilization problem.

4. Conclusion- Endoscope Repairs

The results of this study illustrate that independent servicers are not capable of consistently performing effective endoscope repairs. Although the functionality of nine of the ten repaired endoscopes was improved after repair, *not one met Karl Storz specifications.* The deviations from Karl Storz specifications ranged from minor to major, all of which impact the safety and effectiveness of the devices. For example, one endoscope was completely nonfunctional after repair while others had relatively minor problems in comparison, such as out-of-focus image or misassembly.

KSEA has addressed the more easily quantifiable problems of poor endoscope repair by independent servicers, such as physical damage and optical quality, in this study. What could not be addressed in this limited study is the impact of the materials used by the independent servicers to repair these devices, including adhesives to secure lenses and other components, as well as various grades of stainless steel for shaft replacements. The quality and types of materials used to repair an endoscope can have a serious impact on the device in terms of biocompatibility, functionality and sterilization compatibility.

A good example to illustrate this point is the proprietary adhesive used by Karl Storz to secure various components of both autoclaveable and non-autoclaveable endoscopes. The type of adhesive is especially critical to the compatibility of autoclaveable endoscopes with steam sterilization; wherein the use of the wrong adhesive could render the device nonfunctional after sterilization. The proprietary adhesives have been subjected to extensive testing during validation studies with rigid endoscopes and glutaraldehyde disinfection, and steam (where applicable), ethylene oxide, STERIS®,

STERRAD® and Plazlyte™ sterilization. These studies addressed both materials compatibility and sterility efficacy. Independent servicers do not have access to these adhesives and therefore must substitute other adhesives for those that have been validated by KSEA as acceptable for use with a particular sterilization/disinfection method.

The majority of independent servicers have not conducted sterilization compatibility testing of their adhesives with the new sterilization technologies, e.g., STERIS®, STERRAD® and Plazlyte™, that are quickly replacing ethylene oxide as the sterilization methods of choice (e.g. refer to Attachment 4 for an Advanced Sterilization Products (ASP) position letter and a list of independent servicers that have worked with ASP to conduct material compatibility testing of the adhesives they use for repair with STERRAD®. *Note that there are only four independent servicers in the entire United States that have been "approved" by Advanced Sterilization Products; only one of the independent servicers in this study has conducted material compatibility testing with STERRAD®.*) Therefore the recommended reprocessing instructions in the Karl Storz instruction manual for the rigid endoscopes may not be valid after the endoscope is repaired by an independent servicer, because these recommendations are based upon the materials that Karl Storz uses in its endoscopes. Hence the risk for damage to the endoscope has increased because of use of unapproved adhesives and other materials, thus increasing the risk of injury to the patient.

The specific examples presented in Section I- "Repair and Evaluation of Endoscopes and Instruments", describing Karl Storz endoscopes that were repaired incorrectly by independent servicers, have demonstrated that servicers:

- Do not return endoscopes to their original published specifications
- Do not validate that repaired endoscopes perform according to the manufacturer's specifications
- Do not use proper materials and components to repair endoscopes
- Have limited knowledge of endoscopes

B. Instrument repair

1. Methods

Three damaged endoscopic insulated electrosurgical instruments (models 28090KJ, 28090UL and 28175MS), including two pairs of forceps and one pair of scissors, were sent for repair to the following independent servicers:

- Carefree Surgical Specialties, Inc. in Newcastle, CA
- Mobile Instrument Service and Repair in Bellefontaine, OH.

As with the independent servicers used to repair the rigid endoscopes, these servicers were selected because they are well-known, reputable, established companies that have been used by customers to routinely repair Karl Storz devices. All general aspects of this study were identical to the those outlined for endoscope repair on page 3.

One additional endoscopic non-insulated forceps (model 26167FA) was returned to KSEA for evaluation by a KSEA customer after the instrument was unsatisfactorily repaired by Mobile Instrument Service and Repair.

Each of the first group of three electrosurgical instruments was visually evaluated before being sent out for repair. The remaining pair of forceps that was included in this study was received from the customer only after it had been repaired by the independent servicer, therefore KSEA was not able to evaluate the devices in the "before" condition.

However, all four instruments were evaluated after repair, both visually and functionally. The visual examination included examination of the device for damaged insulation and broken parts. Functionality was determined by manipulation of the device handle and observing the resulting action in the jaws.

2. Results

As illustrated by the summarized results presented in Table 3 (Attachment 1), *every instrument that was repaired by an independent servicer in this study exhibited problems with insulation or basic reassembly.*

Insulated instruments:

The damage to the forceps jaws and scissors blades was satisfactorily repaired. However, the remaining problems pertaining to insulation were not resolved, although the insulation was replaced and the gross damage to the insulation was repaired, e.g., holes and tears.

Insulation problems:

- All three (100%) of the insulated devices did not have adequate insulation. Portions of the shaft, handle, and drawbar were left exposed (see Photos 7 and 8)

Non-insulated instrument

Incorrect Assembly:

- The one pair of noninsulated forceps was incorrectly assembled. The irrigation port was 90° out of position (under the shaft instead of on the side). The jaws of the forceps opened horizontally instead of vertically (see Photo 6 in Attachment 3).

3. Discussion of instrument repair results

All four instruments that were sent to independent servicers for repair were poorly repaired and did not meet Karl Storz specifications. These repairs present serious safety issues to the patient and to the healthcare personnel. As shown in Table 4, the three insulated instruments did not have adequate insulation coverage and the single noninsulated device was completely misassembled. These issues are discussed in more detail below.

Insulation:

Inadequate insulation increases the risk of electrical shock or burns to the patient and healthcare personnel. This is a serious safety issue, since an undetected burn or bowel perforation can lead to serious infections or even death. Injury is even more likely to occur in this case because once the device is returned to the customer, the insulation will be examined for the holes and cracks that were the initial problem, none will be detected and the assumption will be made that the product is safe to use, when in reality it is not. The customer is relying upon the independent servicers to properly insulate all potentially dangerous parts of the instrument, even though the instruments in this study were not.

Incorrect assembly:

This device was assembled in a configuration that has never been seen before on a Karl Storz device. If this device inadvertently made it into the operating room for a surgical procedure, it could present a problem when the surgeon opens the jaws in a constricted space and suddenly finds that they open horizontally, not vertically, as expected. The incorrect assembly of a simple device, once again illustrates the lack of knowledge

regarding device specification, the lack of ability to verify device performance and a lack of repair expertise.

4. Conclusion

The results of this study illustrate that independent servicers are not capable of consistently performing effective instrument repairs. *Not one instrument repair met Karl Storz specifications! All electrosurgical instruments had serious insulation flaws that create a safety hazard.* The deviations from Karl Storz specifications were major, impacting the safety and effectiveness of the devices. All of the electrosurgical devices had inadequate insulation. The misassembly of the one noninsulated device is an excellent example of a complete lack of understanding of the device.

Just as with endoscopes, the independent servicers also use a variety of materials to repair devices that do not meet Karl Storz specifications. The general material issues for endoscopes relating to sterilization that were discussed on pages 9-10, hold true for surgical instruments also. KSEA has conducted all sterilization validation testing for instruments with devices made of the certain grades of stainless steel, types of insulation and adhesives. Any changes to these materials by an independent servicer could invalidate the sterilization/disinfection recommendations found in the device instruction manual. The incorrect selection of surgical grade stainless steel and insulation materials, could also have a negative impact upon device functionality, and biocompatibility.

From a functional perspective, the grade of stainless steel is important for surgical instruments because of the amount of force that forceps jaws or scissors blades encounter during the course of a surgical procedure. Harder grades of stainless steel are used by Karl Storz to manufacture forceps jaws and scissors blades in order to minimize any bending or breakage. Replacement of these parts with softer grades of steel, as could be done by an independent servicer, will have a negative impact upon the safety and performance of the instruments

II. REPAIR AND EVALUATION OF VIDEO CAMERAS

1. Methods

Video camera complaint and repair records were searched for information pertaining to repair issues involving independent servicers. Three complaints and two repair records were found in the last 90 days that showed evidence of repair by independent servicers. Only one of these could be traced to a specific independent servicer (Integrated Medical Systems). The others were identified as a repair by an independent servicer because of the presence of non-Karl Storz parts on the camera. Since these cameras were sent to independent servicers for repair by customers, evaluation of the cameras prior to repair was not possible.

2. Results

A) Customer complaint

A camera (model 20221130) was sent to an independent servicer, Integrated Medical Systems (IMS), for repair for a dark spot in the image and was returned to the customer after repair in a nonfunctional state. Upon a repeated return to IMS, it was again repaired and subsequently returned in a semi-functional state, with problems involving the on-screen menu.

B) Customer complaint

A customer sent a Karl Storz camera head (model 20210101) to an unidentified independent servicer for a complaint of "flashing image" on the monitor. The camera was returned to the customer after repair with the problem still unresolved. The cable had been replaced with a non-Karl Storz cable and the camera cable card edge was "badly corroded", resulting in intermittent noise in the picture. This had occurred twice with this specific camera.

C) Customer complaint

A customer sent a camera (model 20221120) to an unidentified independent servicer to rectify a problem of 'no image". A non-Karl Storz cable had been installed on the camera head, with a power supply failure resulting from improper cable wiring.

D) Repair

This camera (model 20210130) had been sent to an unidentified independent servicer for an undisclosed problem and was then returned to Karl Storz for repair because of a "foggy" image. The device had a non-Karl Storz cable installed. The camera leaked

at the zoom and focus rings as a result of the attempted repair by the independent servicer.

E) Repair

This camera (model 20210120) was also sent to an unidentified independent servicer for an undisclosed problem. The camera cable was replaced with a non-Karl Storz cable. The repair by the independent servicer resulted in head leaks at the front window and the focus and zoom rings. Also, the headboard PCA was dislodged from the sensor and the cable connection was intermittent.

3. Discussion

The cameras in this group were subject to unsatisfactory repair by independent servicers. These were primarily due to lack of expertise in camera repairs and the use of improper materials and components.

It is evident from the product complaint/repair summaries presented in the results section that independent servicers use components, e.g. cables, that do not meet Karl Storz specifications. If an "intermittent" cable, as described in examples B and E, caused an interruption of the image on the monitor during a critical moment in a surgical procedure, such as during cutting of tissue, the results could be disastrous.

Independent servicers could not properly seal two of the cameras, thus impacting the performance of the camera because of moisture in the optics. This is a relatively basic repair and yet it was clear that these independent servicers were not familiar enough with the devices to accomplish it properly. The repair of circuitry and wiring also seemed to be beyond the capabilities of the independent servicers, since two cameras experienced these types of problems after repair.

4. Conclusion

The results of this study illustrate that independent servicers are not capable of consistently performing effective video camera repairs and, because of this, put the patient at unnecessary risk. Although a camera itself is considered to be a low risk device, it is part of a chain of devices that include the light source, endoscope, and camera system. If the camera fails, then the higher risk endoscope has also failed, albeit indirectly. The end result is the same: the surgeon has no image of the surgical site. Therefore, failure of the camera can be a serious safety issue in addition to a performance issue.

Cameras are quite complex devices comprised of a combination of electronic circuitry and optics. Because the camera actually consists of the camera head, power supply,

monitor, etc. it is often necessary to evaluate the entire system to detect the problem in a single component of the system. Based on the evidence presented herein, it is clear that independent servicers do not understand this concept.

As with endoscopes and surgical instruments, the independent servicers also use a variety of materials to repair devices that do not meet Karl Storz specifications. This study revealed that the non-Karl Storz camera cable was a major cause of problems. The corrosion of the card-edge of one camera cable indicated that there was an incompatibility with reprocessing chemicals. If proper material compatibility validation studies for various sterilization/disinfection methods had been conducted, this would not have been an issue.

Karl Storz conducted many studies to ensure that the camera materials are compatible with sterilization and disinfection processes, especially the newer technologies such as STERIS® and STERRAD®. Specifically, Karl Storz worked with Advanced Sterilization for a substantial period of time to develop a STERRAD® compatible camera cable. The results of this study show that independent servicers are not conducting the same types of studies.

III SUMMARY AND RECOMMENDATIONS

KSEA has conducted a two-part study addressing repairs by independent servicers on a variety of Karl Storz products. Firstly, KSEA has conducted a limited study of damaged Karl Storz endoscopes, and insulated and noninsulated instruments that have been sent to specific independent servicers for repair. Secondly, KSEA has reviewed complaint, repair and legal records for evidence of substandard repairs by independent servicers.

The results of the study and the records research revealed that independent servicers are not capable of consistently performing effective medical device repairs and cannot restore Karl Storz devices to the manufacturer's specification. In several instances, devices were returned to the customer in a nonfunctional state, indicating that acceptable device performance was not verified upon completion of the repair. This was found in all device groups that were part of this study: rigid endoscopes, surgical instruments and video cameras. In some instances the improper repair resulted in a potentially harmful device, e.g. electrosurgical devices with inadequate insulation.

The study also showed that there was no difference between the seven independent servicers that were represented: all were equally capable of performing substandard device repairs. The result of this research has demonstrated that independent servicers:

- Do not return devices to their original published specifications
- Do not validate that repaired devices perform according to the manufacturer's specifications
- Do not use proper materials and components to repair devices
- Have limited knowledge of medical devices

Therefore, KSEA recommends that servicers should be subject to the requirements of 21 CFR 820 Quality Systems Regulations in order to reduce the risk to the public health. As a device manufacturer, Karl Storz' experience with the Quality Systems Regulations (and GMPs) has not only ensured that Karl Storz devices are safe and effective, but also has made good business sense by reducing costs and improving efficiency.

Compliance with the Quality System Regulations offers the same general benefits to the independent servicers industry. However, the following sections of the Quality Systems Regulations have particular relevance to independent servicers in light of the findings of this study (see above items following bullet points).

21 CFR 820.25(b) *Training.* Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

21 CFR 820.70 (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications....Where process controls are needed they shall include:...(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples

820.80(d) *Final acceptance activities.* Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot or batch of finished devices meets acceptance criteria.

These specific sections of the Quality Systems Regulation address the problems that currently affect independent servicers in regards to lack of adherence to device specifications and general lack of knowledge of the devices being serviced. In many ways, the independent servicer faces a greater challenge than the original medical device manufacturer: not only must they repair devices that they do not design or manufacture, but they must also service devices from a myriad of different manufacturers, all with different device designs, materials and components.

Compliance of independent servicers with the Quality System Regulation will allow the independent servicer to meet that challenge and reap the same benefits that the original device manufacturer experiences from compliance with the Quality System Regulation: safe and effective devices, cost savings and increased efficiency.

Contact Information:

All repair records are available to FDA by contacting: Marika Anderson, Senior Regulatory Affairs Specialist, Karl Storz Endoscopy-America, Inc., 600 Corporate Pointe Culver City, CA 90230-7600, Phone: 310 410 2731, Fax: 310 410 5519

Best regards,

Marika Anderson
Senior Regulatory Affairs Specialist

Attachment 1

EVALUATION OF RIGID ENDOSCOPES
BEFORE AND AFTER REPAIR BY INDEPENDENT SERVICERS

TABLE #1

DEVICES	SERVICES	PROBLEMS BEFORE EVALUATION	PROBLEMS AFTER EVALUATION
27005B	IMS	Shaft bent, no image	Eyepiece is positioned incorrectly, image indicator in wrong position
27005BA	Endocare	Shaft dented, foggy image	Out of focus. Shaft dented
26006AA	Precision	Eyepiece window broken, no image	Out of focus, bent shaft, eyepiece ID ring on backwards and in wrong position, image indicator in wrong position, angle of view off by -2°
27018A	Fibertech	Shaft crushed	Out of focus, shaft length 1 mm too long, angle of view off by -2°
27018A	Surgitech	Shaft dented and cracked	Out of focus, shaft length 1 mm too long, angle of view off by -4°
7200A	IMS	Shaft dented and cracked	Out of focus
7200A	South Coast	Unknown	Out of focus, gouges at shaft/body junction, distal tip of shaft chipped, distal lens chipped and scratched
7200A	South Coast	Unknown	Out of focus, gouges at shaft/body junction, metal chipped on distal tip, cracked color ring
7200A	South Coast	Unknown	Out of focus, gouges at shaft/body junction, scratched eyepiece, dirty distal lens and shaft, cracked color ring
26006A	South Coast	Unknown	Lens inside eyepiece broken loose, no image

OPTICAL TEST RESULTS OF RIGID ENDOSCOPES
AFTER REPAIR BY INDEPENDENT SERVICERS

TABLE #2

DEVICE/ SERVICER.	ILLUMINATION EFFICIENCY			IMAGING TRANSMISSION			FIELD OF VIEW in degrees		
	repair	reference	Δ %	repair	reference	Δ %	repair	reference	Δ %
27005B IMS	1.01	1.00	1	0.76	1.00	24	69	71	3
27005BA Endocare	0.89	1.00	11	0.82	1.00	18	70	71	.22
26006AA Precision	0.78	1.00	22	0.86	1.00	14	69	73	4
27018A Fibertech	0.47	1.00	**53**	0.90	1.00	10	56	57	1
27018A Surgitech	0.43	1.00	**57**	1.03	1.00	.03	85	56	**29**
7200A IMS	0.67	1.00	**33**	0.99	1.00	1	78	75	3
7200BW So. Coast	0.24	1.00	**76**	0.52	1.00	**48**	98	102	4
7200BW So. Coast	0.63	1.00	**37**	0.43	1.00	**57**	95	102	7
7200BW So. Coast	0.39	1.00	**61**	0.70	1.00	**30**	106	102	4
26006A So. Coast	0.70	1.00	**30**	NA	NA	NA	NA	NA	NA

OPTICAL RESOLUTION TEST RESULTS

(measure of resolution on image axis)

Table #3

Device/ Repair Co.	Resolution (lp/mm)	
	repair	control
27005B IMS	5	5
27005BA Endocare	5	5
26006AA Precision	5	5
27018A Fibertech	4	4
27018A Surgitech	5	4
7200A IMS	5	5
7200BW South Coast	7	8
7200BW South Coast	8	8
7200BW South Coast	3	8
26006A South Coast	NA	NA

EVALUATION OF INSTRUMENT
BEFORE AND AFTER REPAIR BY INDEPENDENT SERVICERS

TABLE #4

DEVICES	SERVICES	PROBLEMS BEFORE EVALUATION	PROBLEMS AFTER EVALUATION
28090KJ Insulated forceps	Carefree	Broken jaw link, jaw will not stayed closed Insulation damaged on handle	No insulation on drawbar or handle
28090UL Insulated forceps	Carefree	Insulation damaged	Inadequate insulation on shaft-leaves a small portion exposed above jaws Insulating boat missing where shaft and handle meet
28175MS Insulated scissors	Mobile Instrument Repair	Scissor blades are dull and stick because they are slightly bent	No insulator on drawbar at handle
26167FA Noninsulated forceps	Mobile Instrument Repair	Unknown	LUER port out of position 90° Forceps jaws open horizontally instead of vertically

2

Attachment 2

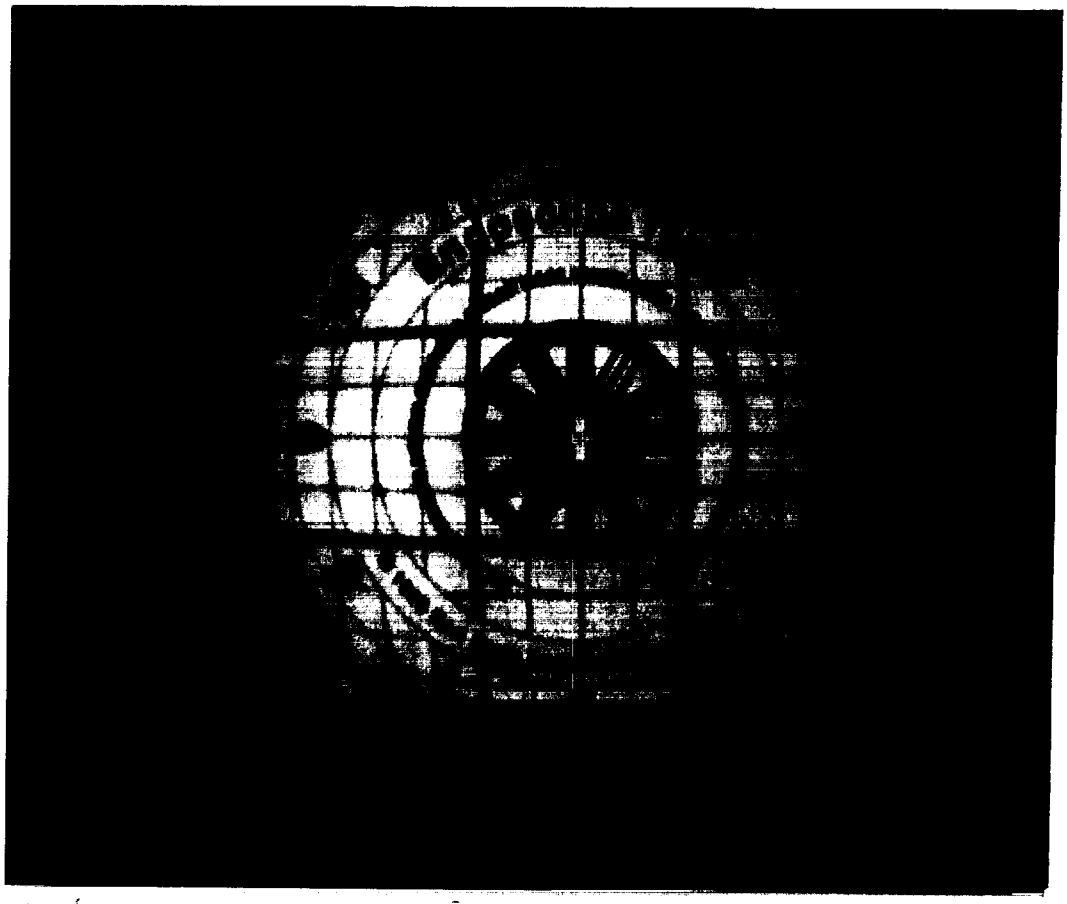

Fig 1

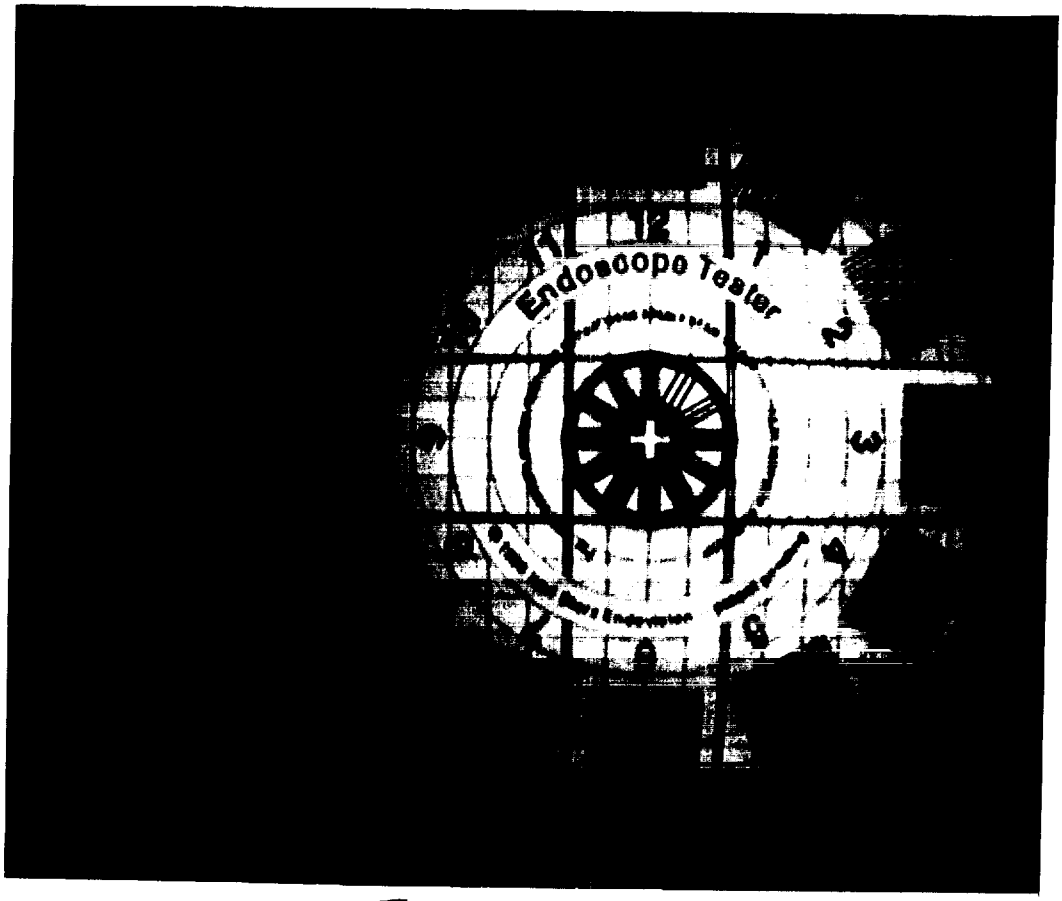

Fig 2

3

Attachment 3

Photo #1

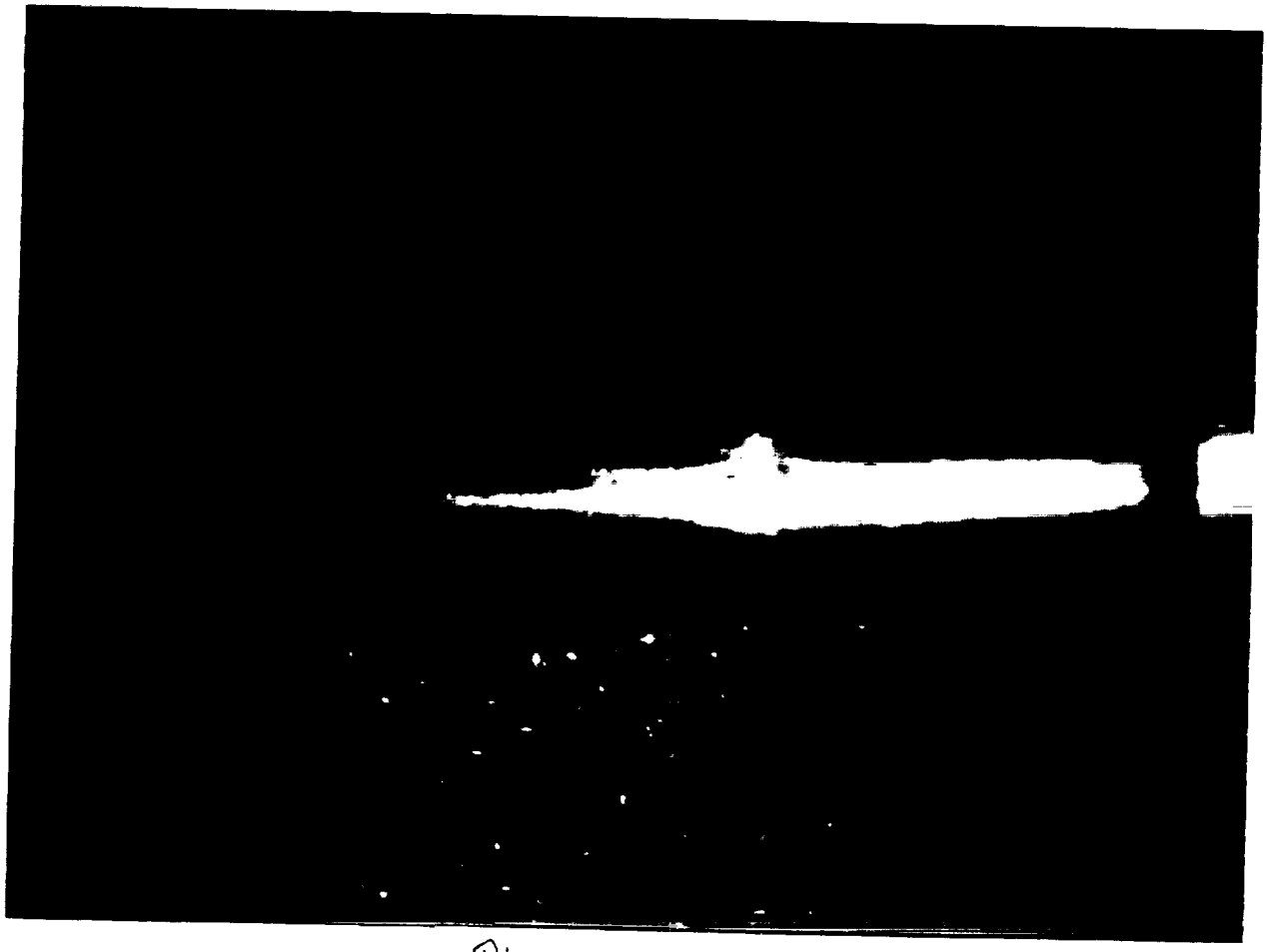

Photo #2

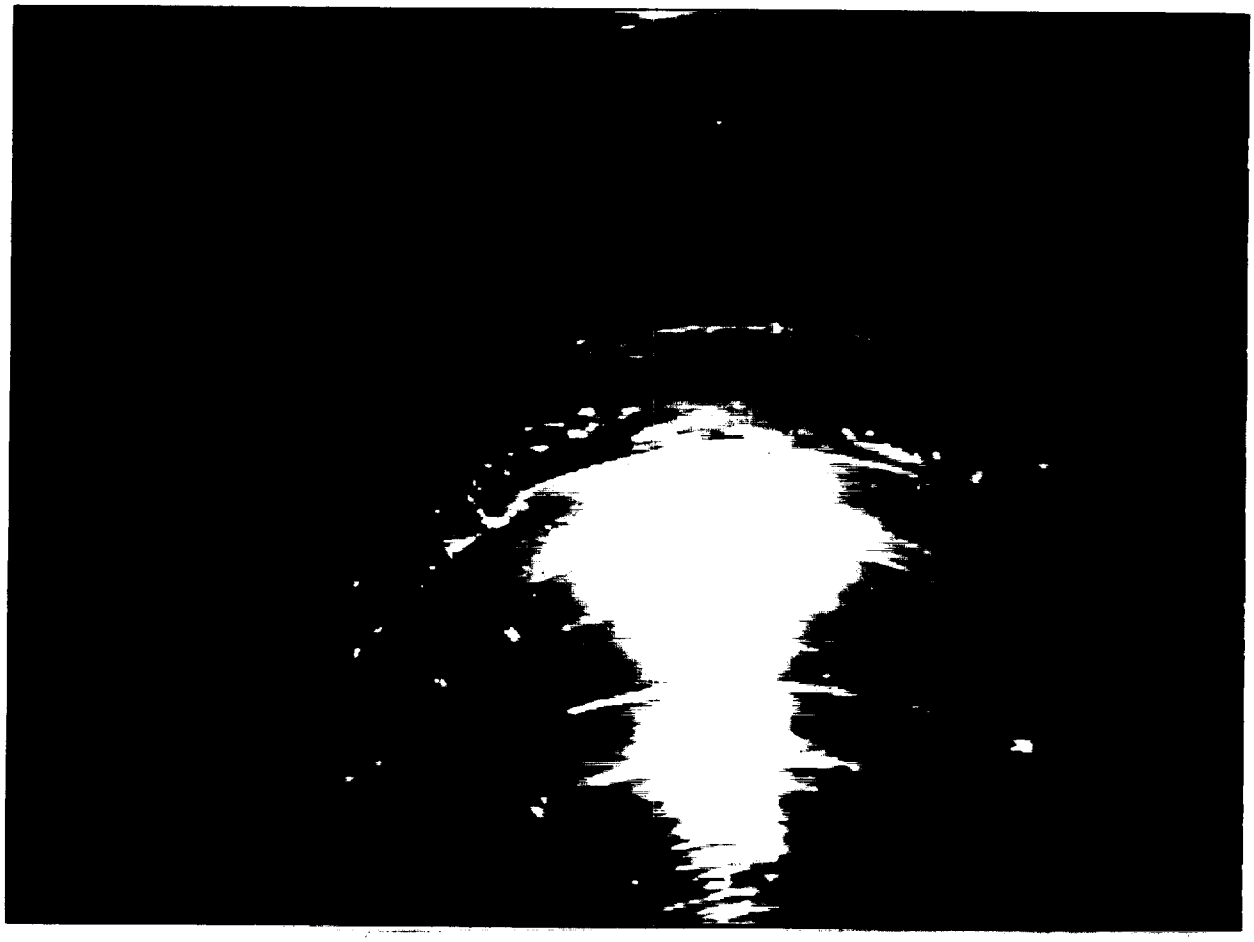

Photo # 3

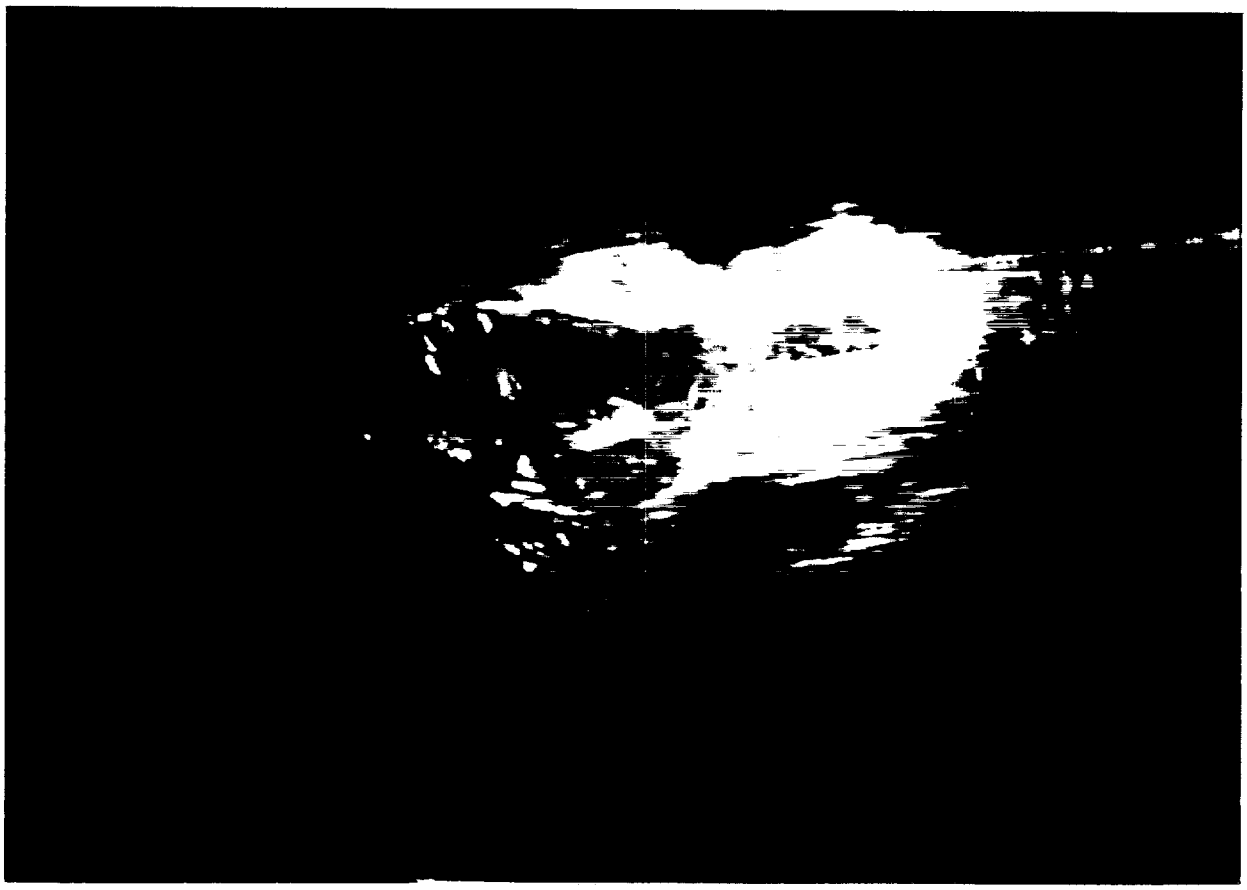

Photo # 4

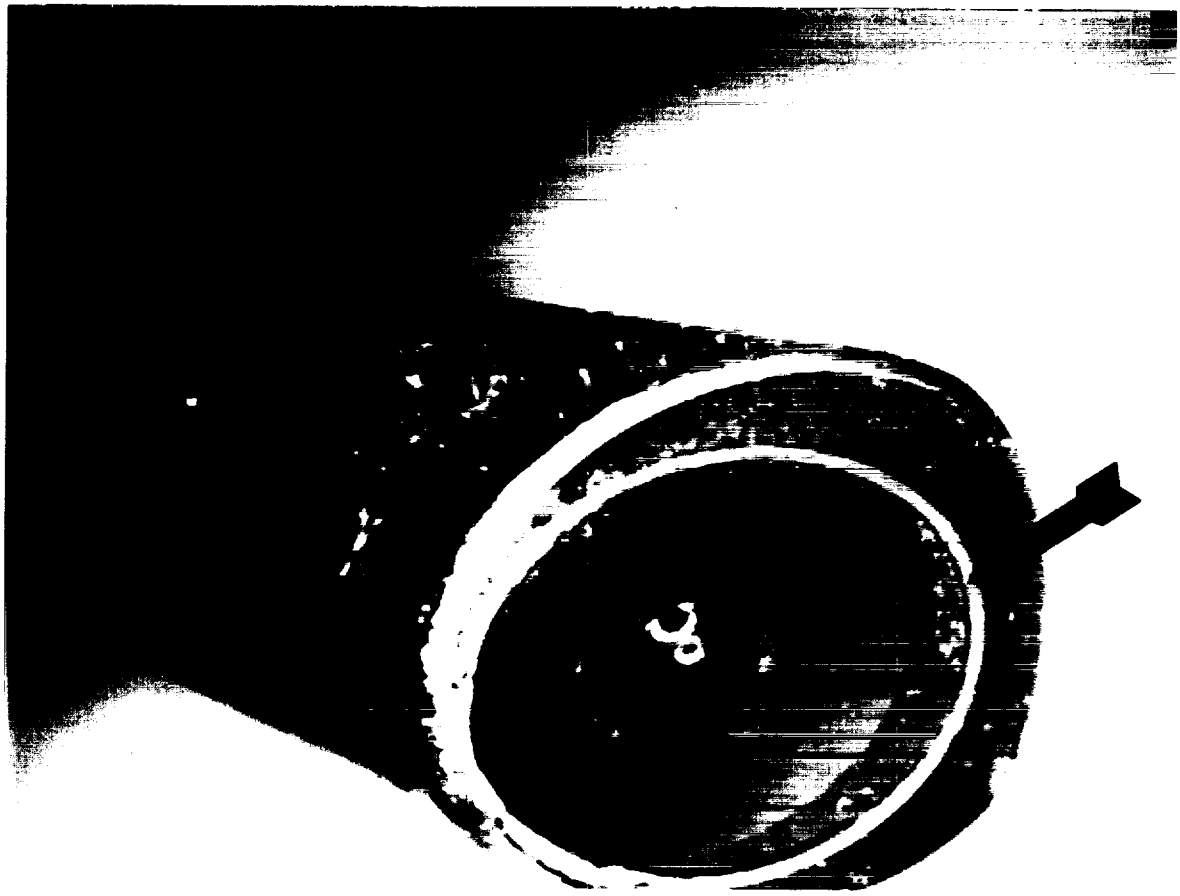

Photo # 5

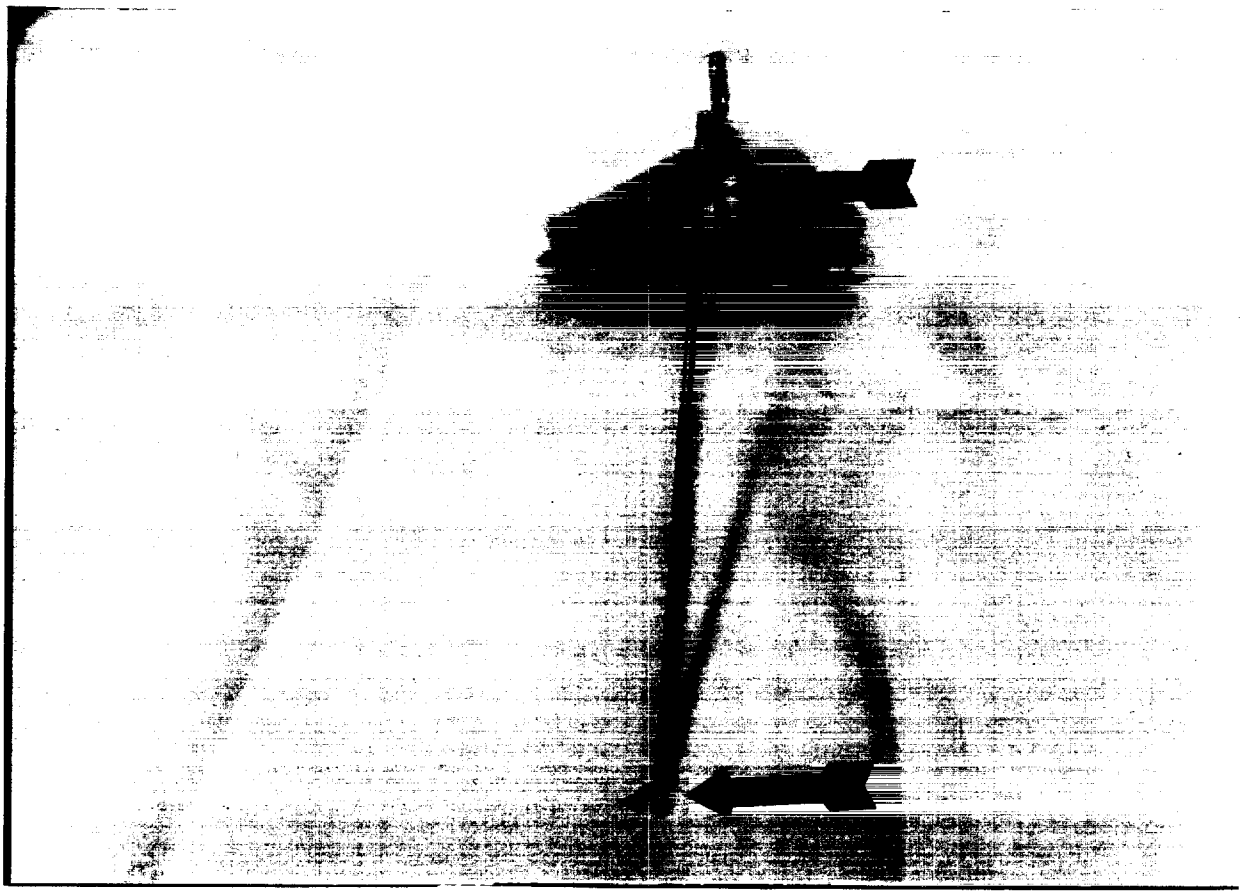

Photo # 6

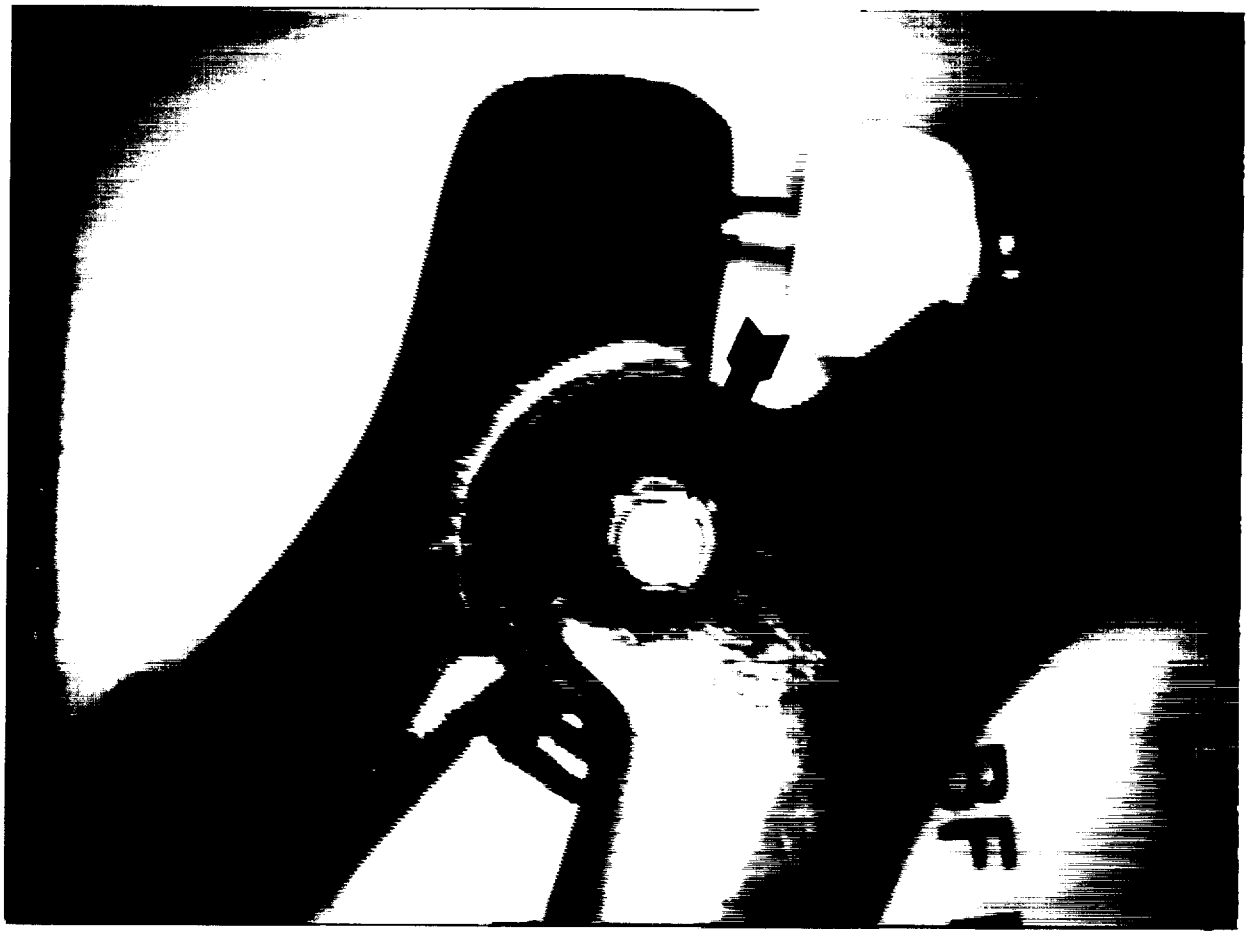

Photo #7

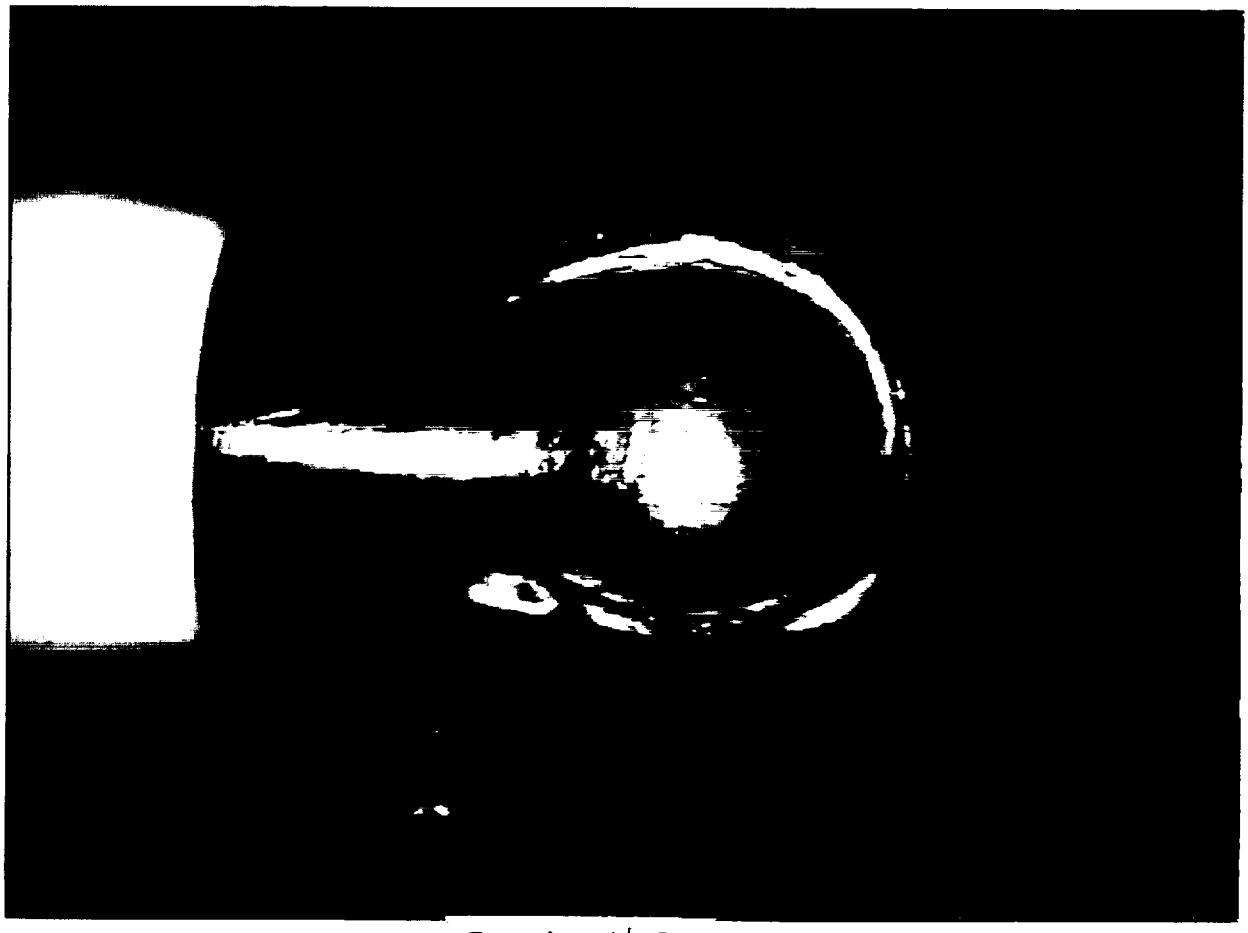

Photo #8

Attachment 4

ADVANCED STERILIZATION PRODUCTS

STERRAD® System Compatibility

Advanced Sterilization Products' (ASP) Materials Compatibility Testing Program involves testing devices typically to 100 STERRAD System cycles followed by functionality testing and evaluation by both the Medical Device Manufacturer and ASP. Once compatibility is established, devices operated by the STERRAD System user must be handled and processed according to the instructions from the Medical Device Manufacturer. In the event a device requires repair or refurbishment, the device should be restored to its original manufacturer's specifications using only STERRAD System compatible components. In general, this applies to authorized repairs made by the original manufacturer. Repairs made by unauthorized, or third party repair services to STERRAD System compatible devices are not recommended unless the third party repair service has been evaluated by ASP and determined to be capable of performing STERRAD System compatible repairs and the device is restored to the original manufacturer's specifications. For further information, please contact ASP (714) 453-6344.

A DIVISION OF Johnson & Johnson MEDICAL, INC.
33 Technology Drive, Irvine, CA 92718 (714) 581-5799 FAX (714) 581-5997

Attached is a list of third party repair shops that we have worked with. We typically tested adhesive samples and/or rigid scopes sealed with their adhesives for them. We also sent them a technical bulletin listing the 36 adhesives that ASP has tested and their relative compatibility with the STERRAD® System. The repair shops should have a good understanding as to the types or kinds of adhesive that are compatible with our sterilization system.

Mobile Instrument Service and Repair
Lee Ann Norviel
333 Water Ave.,
Bellfontaine, OH 43311
800-722-3675 X 130

MediVison
Scope Service Center, Inc.
1440 S. State college Blvd. #1D
Anaheim, CA 92806
Alex Vayser
714-563-2772

Precision Medical Inc.
23181 Verdugo Drive, #103B
Laguna Hills, CA 92653
800-365-4451
Sean McKelvey

Surgical Optics
10071-B Bines Blvd.
Pembroke Pin, Fl 33024
Peter Bodor
1-800-371-9995

Federal Express®

STORZ
Karl Storz Endoscopy

Karl Storz
Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600
Phone 310 558 1500
Toll Free 800 421 0837
Fax 310 410 5525

TO

Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

KARL STORZ ENDOSCOPY AMERICA
600 CORPORTE POINTE
CULVER CITY CA 90230
(310)558-1500

SHIP DATE: 23MAR98
ACC # 1604478420

ACTUAL WGT: 1 LBS MAN-WT

SEE ADDRESS LABEL ON PACKAGE FOR
THIS SHIPMENT TO MD 20857

4136 7812 2686 FEDERAL EXPRESS

4136 7812 2686

REF: MICHAEL/20857

STANDARD OVERNIGHT TUE

cad # 0025596 23MAR98

Deliver by:

TRK# 4136 7812 2686 FORM 0201

24MAR98

IAD AA

20857 -MD-US 19 GAIA

#145390 Format# 077 G.S.I. 4/94

23